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Laws, Regulations, Policies and Procedures for Drug Applications

- *Code of Federal Regulations* for Investigational New Drugs (INDs), New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs)
- Manual of Policies and Procedures (MaPPs)

The mission of FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook. *The Federal Food, Drug, and Cosmetic Act* is the basic food and drug law of the U.S. With numerous amendments it is the most extensive law of its kind in the world. The law is intended to assure the consumer that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive.

Code of Federal Regulations for Investigational New Drugs (INDs), New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs)

The following *Code of Federal Regulations* sections provide regulations for INDs and NDAs. All parts of section 21 of the *Code of Federal Regulations* are also available.

- CFR Sections for INDs
- CFR Sections for NDAs
- CFR Sections for ANDAs

Manual of Policies and Procedures (MaPPs).

The following MaPPs provide official instructions for internal practices and procedures followed by CDER staff to help standardize the IND and NDA review process. All CDER MaPPs are available from the MaPP Index

webpage.

- MaPPs for INDs
- MaPPs for NDAs
- MaPPs for ANDAs

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